IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
Prasad DEVARAJAN et al.	:	Confirmation No: 2792
Serial No.: 10/811,130	:	Group Art Unit: 1641
Filed: March 26, 2004	:	Examiner: FOSTER, Christine E.

A METHOD AND KIT FOR DETECTING THE EARLY ONSET OF RENAL TUBULAR CELL INJURY

SUPPLEMENTAL DECLARATION UNDER 37 CFR 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Prasad Devarajan and Jonathan Barasch, do hereby declare as follows:

1. We are the joint inventors of the subject matter described and claimed in the above-identified patent application.

2. I, Prasad Devarajan, hold an undergraduate degree in Biology and a Medical Doctor (M.D.) degree from Bombay University, India. I also completed graduate research in renal disease in the Department of Physiology, and a residency in Pediatrics at SUNY at Stony Brook, NY. I also completed a fellowship in Nephrology at Yale University, and completed an NIH-sponsored research fellowship in renal disease at Yale. I have been conducting research in the field of renal disease since 1985. I am presently the Louise M. Williams Endowed Chair, Professor of Pediatrics, Professor of Developmental Biology, Director of Nephrology and Hypertension, Director of Nephrology Clinical Laboratories, CEO of Dialysis Unit, at Cincinnati Children's Hospital Medical Center and the University of Cincinnati School of Medicine, Cincinnati, OH.

I am an expert reviewer of grant applications in the field of renal diseases for the NIH and several other national and international organizations. I am an expert reviewer of publications submitted to more than 20 scientific and medical journals in the field of renal disease. I am a member of the Editorial Board

of key journals in the field of renal disease. I am on the Advisory Board and Research Committees of the American Society of Nephrology, American Society of Pediatric Nephrology, International Acute Kidney Injury Network, and the National Institutes of Health in the field of renal disease.

3. I, Jonathan M. Barasch, hold an undergraduate degree in Biochemistry from Dartmouth College and a PhD and Medical Doctor (M.D.) degrees from the College of Physicians and Surgeons. I also completed a residency in Internal Medicine and a fellowship in Clinical Nephrology at Columbia-Presbyterian Medical Center ("Columbia-Presbyterian") in New York. I have been conducting research in nephrology since 1990. I am currently Associate Professor of Medicine and Cell Biology at Columbia University ("Columbia"), and an Assistant Attending Physician in Medicine at Columbia-Presbyterian. I am also the Director of the Research Track of the House Staff Training Program at Columbia.

4. Accompanying the previous response filed December 9, 2009, I, Prasad Devarajan, and I, Jonathan M. Barasch, submitted the Declaration Under 37 CFR 1.132 ("132 Declaration") that was executed December 9, 2009 and December 8, 2009, respectively.

5. Our 132 Declaration states at paragraph 10:

> "Second, and importantly, the NGAL:MMP-9 is a cancer marker that results from chemical linkages. These chemical (disulfide linkages) are even more common in rodents than in humans (and Matthaeus used rodents) because in rodents there is an extra-unpaired cysteine residue in rodent NGAL (but not in the human) and this amino acid is involved in cross-linking. We would conclude that Matthaeus is focused on the biology of MMP-9 activity in the body of the kidney, prominent in rodents."

6. It was brought to our attention by a communication received from the firm of Gifford, Krass, Sprinkle, Anderson & Citkowski, P.C. ("the Gifford communication", identified in a supplemental Information Disclosure Statement filed March 26, 2010), that the statement in paragraph 10 of the 132 Declaration that the "... chemical (disulfide linkages) are even more common in rodents than in humans (and Matthaeus used rodents) because in rodents there is an extra-unpaired cysteine residue in rodent NGAL (but not in human) and this amino acid is involved in cross-linking", is incorrect.

7. After reviewing the Bundgaard et al. reference ("Molecular cloning and expression of a cDNA encoding NGAL: a lipocalin expressed in human neutrophils." Biochem Biophys Res Commun. 1994 Aug 15; 202(3): 1468-75) mentioned in the Gifford communication, we agree that the statement from paragraph 10 of the 132 Declaration, quoted above in paragraph 5, is incorrect, and agree that it is the human NGAL that has an extra unpaired cysteine residue, and that the rodent NGAL does not.

8. At the time the aforementioned 132 Declaration was signed, the above quoted statement made by us in paragraph 10, regarding chemical (disulfide linkages) being even more common in rodents than in humans, was believed to be true and, therefore, was not made with an intent to deceive. Further statements that were made in the 132 Declaration, in view of the statement in Matthaeus that NGAL has been shown to occur in disulfide-linked complexes with MMP-9 and TIMP-1, also were believed to be true, were not made with an intent to deceive, and were not adversely affected by the statement made by us in paragraph 10 of the 132 Declaration quoted above in paragraph 5.

9. We further declare that all statements made of our knowledge are true and that all statements made on information and belief are believed to be true; further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 USC 1001 and may jeopardize the validity of the application or any patent issuing thereon.

Date	Prasad Devarajan
Jan 31 2011	
Date	Jonathan M. Barasch

18 USC 1001: *"(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—*

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry:

shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both. If the matter relates to an offense under chapter 109A, 109B, 110, or 117, or section 1591, then the term of imprisonment imposed under this section shall be not more than 8 years.

(b) Subsection (a) does not apply to a party to a judicial proceeding, or that party's counsel, for statements, representations, writings or documents submitted by such party or counsel to a judge or magistrate in that proceeding.

(c) With respect to any matter within the jurisdiction of the legislative branch, subsection (a) shall apply only to—

(1) administrative matters, including a claim for payment, a matter related to the procurement of property or services, personnel or employment practices, or support services, or a document required by law, rule, or regulation to be submitted to the Congress or any office or officer within the legislative branch; or

(2) any investigation or review, conducted pursuant to the authority of any committee, subcommittee, commission or office of the Congress, consistent with applicable rules of the House or Senate."